

SAFEGUARDS

CONSUMER GOODS AND RETAIL

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EU AMENDMENTS TO MEDICAL DEVICES REGULATIONS CONCERNING HAZARDOUS SUBSTANCES

On 12 March 2014, the EU Parliament completed a final vote on a proposal for a regulation regarding medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009¹. An important revision concerns the use of phthalates in medical devices.

The proposed amendment requires the ban of substances that are classified or recognized as

- Carcinogenic, Mutagenic or toxic to Reproduction 1A or 1B (CMR, in accordance with Regulation (EC) No 1272/2008), or
- Endocrine Disruptors (EDCs)

in concentrations above 0.1% by mass of homogeneous material, contained within medical devices that come into contact with the human body. The regulation states that such substances would be phased out within 8 years, should safer alternatives become available.

If specific medical devices are meant for the treatment of children, pregnant or nursing women, phthalates, which are classified as CMR, should be banned as of 1 January 2020. The only exceptions are the cases when the manufacturer has the ability to prove that no other safer substances are available, in which case the device's labelling and (or) packaging needs to clearly indicate the presence of substances that are classified CMRs 1A or 1B or as EDCs.

The proposed Regulation also covers devices that contain or consist of nanomaterials that can be released in the human body. In accordance with the amendments, manufacturers are required to incorporate evidence as part of the device's technical documentation or instructions, which demonstrates that the use of nanomaterials is in compliance with safety and performance requirements and standards.

SGS is committed to keeping you up to date on the latest regulations and policies concerning the use of hazardous substances in consumer products. Furthermore,



¹ [\(EC\) No 1223/2009](#)

through its global expertise and network of chemical labs, SGS can support you in ensuring your products comply with relevant hazardous substances requirements on all relevant markets around the world. Whether you are in need of hazardous substances testing or other third party verification, certification or inspection services, SGS is ideally positioned to satisfy all your business's needs.

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